

Notice of Allowability

Application No.

10/633,449

Examiner

Sang Nguyen

Applicant(s)

SHARPE ET AL.

Art Unit

2877

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 03/23/06.
2. ☒ The allowed claim(s) is/are ⁴⁻⁸~~4-8~~ and ~~10-20~~ have been renumbered as indicated claims 1-16.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
- * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|---|--|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date _____. |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____. |

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Mrs. Sandy Zaradic (Reg. No. 45,997) on June 2, 2006.

The application has been amended as follows:

Claims 1-3 and ⁹~~10~~ have been canceled.

Please, amend claims 4, 10, 15, and 17 as the following amendment 02/01/06:

4. (currently amended) The A method for determining a smoothness index of a metered dose container having an inner core ~~according to claim 3,~~ **comprising the steps of:**

a) subjecting said inner core of said metered dose container containing at least one pharmacologically active agent, wherein the **at least one pharmacologically active agent is a** corticosteroid is selected from the group consisting of mometasone furoate anhydrous; beclomethasone dipropionate; budesonide; fluticasone; dexamethasone; flunisolide; triamcinolone; (22R)-6 α , 9 α -ditluoro-11 β , 21-dihydroxy-16 α , 17 α -propylmethylenedioxy-4-pregnen-3, 20-dione; and tipredane, **to reflected light photomicrography to obtain a digital image containing a plurality of pixels of said inner core;**

b) determining from said digital image the brightness of each of said pixels and quantifying said brightness by assigning an integer value thereto, wherein said value corresponds to an amount of brightness: and

c) comparing said brightness of said pixel to a reference standard to determine the smoothness index of said inner core of said metered dose container.

10. (currently amended) The A method for determining a smoothness index of a metered dose container having an inner core ~~according to claim 9~~, comprising the steps of:

a) subjecting said inner core of said metered dose container containing at least one pharmacologically active agent, wherein the at least one pharmacologically active agent is a β -agonist selected from the group consisting of albuterol, terbutaline, salmeterol, bitolterol, formoterol, eFormoterol, 2(1H)-Quinolinone, 8-hydroxy-5-[1-hydroxy-2-[[2-(4-(methoxymphenyl)-1-methylethyl)amino]ethyl] monohydrochloride, [R-(R*,R*)]-, to reflected light photomicrography to obtain a digital image containing a plurality of pixels of said inner core;

b) determining from said digital image the brightness of each of said pixels and quantifying said brightness by assigning an integer value thereto, wherein said value corresponds to an amount of brightness: and

c) comparing said brightness of said pixel to a reference standard to determine the smoothness index of said inner core of said metered dose container.

15. (currently amended) The A method for determining a smoothness index of a metered dose container having an inner core ~~according to claim 2~~, comprising the steps of:

a) subjecting said inner core of said metered dose container containing at least one pharmacologically active agent, wherein the at least one pharmacologically active agent is selected from the group consisting of ipratropium bromide, oxitropium bromide, sodium cromoglycate, nedocromil sodium, montelukast, zafirlukast, pranlukast, bambuterol, fenoterol, clenbuterol, procaterol and broxyterol, to reflected light photomicrography to obtain a digital image containing a plurality of pixels of said inner core;

b) determining from said digital image the brightness of each of said pixels and quantifying said brightness by assigning an integer value thereto, wherein said value corresponds to an amount of brightness: and

c) comparing said brightness of said pixel to a reference standard to determine the smoothness index of said inner core of said metered dose container.

17. (currently amended) The A method for determining a smoothness index of a metered dose container having an inner core ~~according to claim 2~~, comprising the steps of:

a) subjecting said inner core of said metered dose container containing at least one pharmacologically active agent, wherein the at least one pharmacologically active agent is selected from the group combination of a corticosteroid and a β -agonist,

to reflected light photomicrography to obtain a digital image containing a plurality of pixels of said inner core;

b) determining from said digital image the brightness of each of said pixels and quantifying said brightness by assigning an integer value thereto, wherein said value corresponds to an amount of brightness; and

c) comparing said brightness of said pixel to a reference standard to determine the smoothness index of said inner core of said metered dose container.

Allowable Subject Matter

Claims 4-9, and 11-20 are allowed.

The following is an examiner's statement of reasons for allowance:

In independent Claims 4, 10, 15, and 15 are allowed over the prior art of the record for the reasons set forth in the previous Office action on 08/01/05.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sang Nguyen whose telephone number is (571) 272-2425. The examiner can normally be reached on 9:30 am to 7:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gregory J. Toatley, Jr. can be reached on (571) 272-2800 ext. 77. The fax

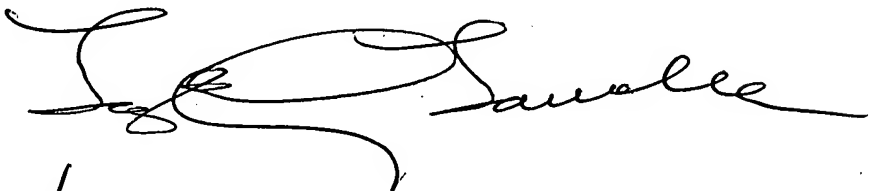
Art Unit: 2877

phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

June 2, 2006

SN
Sang Nguyen
Patent Examiner


for Gregory J. Toatley, Jr.
Supervisory Patent Examiner
Art Unit 2877
Technology Center 2800